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(54) **A DEVICE FOR ARRANGEMENT IN VAGINA FOR PREVENTION OF INVOLUNTARY URINATION
WITH FEMALES AND AN APPLICATOR FOR USE IN INSERTION OF THE DEVICE**

VORRICHTUNG ZUM ANORDNEN IN DER VAGINA ZUR VERMEIDUNG UNBEABSICHTIGTEN
HARNLASSENS, SOWIE EIN ZUM EINSETZEN DIESER VORRICHTUNG ZU VERWENDENDER
APPLIKATOR

DISPOSITIF DESTINE A S'INTRODUIRE DANS LE VAGIN AFIN D'EMPECHER LES MICTIONS
INVOLONTAIRES CHEZ LA FEMME, ET APPLICATEUR PERMETTANT SON INTRODUCTION

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US-A- 4 019 498 **US-A- 4 139 006**
US-A- 5 036 867

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Description

The present invention relates to a device for prevention of involuntary urination in a female, comprising an elastic body made of a compressible material designed for arrangement in the vagina for compressive action on and support of the neck of the bladder, said body including at least two projecting legs joined in a flexible base and is dimensioned in such a way that in the non-deformed state of the body, the longest distance between the free ends of at least two legs exceeds the distance between the anterior wall and the posterior wall of the vagina, so that after insertion of the body into the vagina in an elastically deformed state with the legs bent in a direction towards each other, an active pressure is exerted on the neck of the bladder.

Stress incontinence is a nuisance experienced by up to one third of all women at some time or other during their lives.

Stress incontinence is often caused by a weakening or lack of control of the musculature of the pelvic floor, which results in the lack of support of the bladder neck and closure of the urethra.

Severe cases of stress incontinence are normally relieved by surgical intervention, while minor cases of stress incontinence can often be fully or partially relieved by training or retraining of the pelvic musculature.

Training or retraining of a pelvic muscle may, however, extend over many months and, as mentioned, may not in all cases relieve the problem completely.

It is therefore of great importance to find a product which can relieve stress incontinence.

The use of sanitary towels and napkins for relieving the inconveniences connected with involuntary urination is generally known. This, however, is a method associated with great disadvantages for the woman, as the sanitary towels are unhandy and voluminous, among other things.

Besides, it is known that stress incontinence may be relieved by the use of a tampon-like device which is arranged in the vagina for compressive action and support of the neck of the bladder.

Such a device for relief of stress incontinence is known from, for example, US patent No. 4 019 498. This device consists of a body of compressible elastic material which is compressed and then placed in a bag. The bag with the body is inserted in the vagina, whereupon the bag is punctured. The body will then press against the neck of the bladder and in reality block the urethra. This method partly involves a cost-increasing component - the bag - and partly there is a risk of damaging the vagina and adjacent tissue when puncturing the bag.

Furthermore, it is impossible or difficult to adjust the position of the body after mounting in the vagina. Additionally, the body acts purely by the compressibility of the material, for which reason it is necessary to manu-

facture it in several different sizes.

EP-A-363421 also describes a device for arrangement in a woman's vagina with the object of relieving incontinence. This device also has the disadvantage that it acts as a support to the bladder neck merely in consequence of the compression taking place depending on the size of the vagina and the size of the body.

It is therefore also in this case necessary to manufacture different sizes to compensate for the different vaginal diameters.

Finally, EP-A-264258 and the equivalent US-A-5,036,867 describes an incontinence device of the kind defined above - specifically for use in vaginal and rectal prolapse - designed as a U-shaped body with a resilient base portion forming an arch which in use is adjacent the cervix of the uterus and interconnects two opposing limbs. This device acts by lifting the neck of the bladder, wherein, after having been introduced and arranged relatively far into the vagina close to the cervix, the body returns to its original form due to the spring action provided by the resilience of the base portion, and one limb which is designed with a forked structure, bears against the bladder/neck of the bladder which is lifted, whereby continence is obtained.

This is thus a relatively rigid structure, which is also designed in rather large dimensions.

This device, as well, is required to be manufactured in different sizes to compensate for the different vaginal diameters, as its lift is exclusively due to its shape, just as it is uncomfortable to wear owing to its rigid and fairly large structure.

A common feature of the above incontinence products is thus that it is necessary to manufacture the product in many different sizes to compensate for the various vaginal diameters.

This is partly economically inappropriate, and partly the body will not have an optimum function even after careful selection of size according to a woman's vaginal diameter, as the support by the bodies of the bladder neck will vary according to the physical posture of the woman and the state of tension of her pelvic muscle. There is thus a great risk that by use of the above-mentioned devices, the woman will still suffer from involuntary urination, and/or that the device will cause inconvenience, pain or even damage the vaginal mucous membrane, when the woman is in physical movement or tightens her pelvic musculature.

Thus, the known devices are economically unsuitable, just as they do not have an optimum function throughout their service life.

It is the object of the present invention to provide a device which comfortably relieves the nuisances indicated and thus secures the woman an optimum support regardless of her physical condition and which is at the same time easy to handle.

The device according to the present invention is characterized in that the body is made of a porous material having such a compressibility that, at a com-

pression of each leg to 50 per cent of its total thickness measured before compression, the compressive strength of the body is in the interval of 5-40 N, preferably 10-20 N, so that by deformation of the legs in said elastically deformed insertion state to come into contact with each other on the mutually facing sides the compressible material is compressed to provide an increased elastic force of restitution in the interval of 1-10 N - preferably 1-5 N.

When using the device according to the invention, the compressive and elastic properties of the body are thus utilized together with its properties of restitution, the latter property arising when the legs of the body are pressed towards each other and will attempt to straighten out after insertion into the vagina.

Thus the neck of the bladder is partly supported by the action of the expansion force caused by compression of the body's material in the vagina between the anterior and posterior walls of the vagina and partly by the action of the force of restitution because the folded/bent-in body will attempt to straighten out between said walls.

The combination of the force of restitution and the force of expansion ensures that the product adapts to the varying spatial conditions in the vagina and always provides support for the bladder neck without blocking the urethra. The combination of the two forces also ensures that the product does not become unnecessarily large.

It will thus be possible to keep the resulting support of the bladder neck more stable in case of variations of the vaginal diameter than with the known products.

This means that by use of the device according to the invention, it is possible to obtain a substantially optimum support of the bladder neck without risking exposure of the user to substantial inconveniences or pain or risks of damage to the vaginal mucous membrane.

Additionally, as a consequence of the above, it is possible to manage with a smaller number of sizes for the same user group, just as the product will be easier to insert and remove, as the device has smaller dimensions than the known ones to obtain a more optimum support.

As the body according to the present invention will spontaneously bend in the flexible base in case of folding, the body is easy to handle and to use correctly by the user herself.

Preferably, the device comprises two or three, particularly two, projecting legs which project at a mutual angle of more than about 30°, especially between 90° and 150°.

The device according to the invention may be provided with projecting legs which have a circular cross-section or are wedge-shaped in their outer shape.

In another preferred embodiment, the legs may be provided with a recess on the side facing the urethra and the neck of the bladder and have cushions formed on the opposite side. This makes it possible for the body

to cradle the urethra/bladder neck, and it achieves greater compressive strength.

Additionally, on the side intended to face away from the urethra, the body may be provided with ribs in the flexible base periphery. This achieves a greater spring effect.

As a further possibility, the body may be hollow.

This has the result that the body cradles the urethra, as it is compressed most easily at the middle, and as the cross-section of the vagina is substantially shaped like a figure of eight, for which reason the body bears against the walls of the vagina to a higher degree. Additionally, the body need not be oriented at insertion.

The body may additionally be coated fully or partially with an elastic polymer film, such as polyethylene, polypropylene or polyvinyl chloride.

By coating with an elastic film, for example in the flexible base area, it is thus possible to increase the force of restitution of the body without changing the compressive properties of the legs.

The device according to the invention may be made of one or more materials, comprising porous materials selected among polyvinyl alcohol or polyurethane, and wherein the compressive strength of the body is in the interval of 5-40 N - preferably 10-20 N - at a compression of the body to 50% of its thickness measured before compression.

The force of restitution of the body is in the interval of 1-10 N - preferably 1-5 N. The density is in the interval of 0.15-0.30 g/cm³ - preferably about 0.20 g/cm³.

The invention also relates to the combination of the device as defined herein before with an applicator for use at insertion of the device. According to the invention this combination is characterized in that the device comprises a bevel or a recess in the angle between the projecting legs, and that the applicator comprises an elongated member with a proximal end and with a substantially rod-shaped distal end portion for abutment with said bevel or recess for arrangement of the device in the vagina.

The invention will now be described in further detail below with reference to the drawing, in which

Figs. 1-3 show a front and a side elevation and a perspective view of a first embodiment of the device,

Figs. 4-6 show an embodiment having three legs, Figs. 7-12 show a third embodiment of the device, Fig. 13 shows the arrangement of the device in the vagina for control of incontinence, shown in a sagittal cross-section,

Figs. 14-17 show an embodiment of an applicator for use in the arrangement of the device in the vagina, and

Fig. 18 another applicator embodiment.

Figs. 1-3 show a body 1 having a flexible base 2 and two projecting legs 3 positioned in the same plane.

The legs 3 have a circular cross-section, but may also have other cross-sectional shapes, such as oval, rectangular, etc.

The angle A between the two legs 3, measured between their axes of symmetry a and b is in the interval of 30°-180°, preferably 90°-150°, and depends on the length of the legs 3. Thus, a large angle renders possible a shortening of the length of the legs - all other things being equal - to obtain the same supporting effect.

The surface of the body 1 is smooth, and the angle between the two legs 3 may accommodate a plateau, a bevel or a recess 4, which an applicator (Fig. 14) may abut to facilitate arrangement of the body in the vagina. One leg or both legs 3 may be provided with a string 5 to facilitate removal of the body from the vagina and insertion of the body into the vagina in connection with the use of an applicator.

The diameter of the legs 3 of the body and the flexible base 2 is in the interval of 20-50 mm, preferably 25-35 mm, while the length of the legs 3, where they are measured as the distance between the end point (a) of a leg and the point (b) determined as the point in which the axes of symmetry of the legs intersect each other, is in the interval of 30-70 mm, preferably 40-50 mm, these dimensions measured with the device 1 in a humidified state.

Before arrangement of the body 1 in the vagina, it is humidified, and the two legs are bent towards each other and pressed into the vagina with the arcuate portion first, where the legs will attempt to unfold and the compressed material will seek back to its state of rest. One leg 3 will press against the anterior wall of the vagina and against the bladder neck and support it, while the other leg 3 bears against the posterior vaginal wall.

The body 1 will follow the movements and dimensional changes occurring in the vagina, partly as a consequence of compression/decompression and partly owing to the force of restitution deriving from the two legs 3 of the body.

Figs. 4-6 show another embodiment, wherein the body 11 is provided with three legs 13, but otherwise has the same characteristic features as the one shown in Figs. 1-3.

The angle B between two legs measured from above (Fig. 5) is 120°.

When arranging this embodiment in the vagina, there is less tendency for the body 11 to "overturn", just as it is easier to position the body, as it need not be oriented.

The device 11 may also be manufactured with more than three legs 13 so that it almost assumes the characteristic of an "octopus".

When using an applicator as shown in Figs. 14-18, it is made to abut the recess 14 of the body 11, and the string 15 from the latter is pulled up over the other end of the applicator.

Figs. 7-12 show a third embodiment of the body 21. Here shown with two legs 23, but could well have three or more legs.

Each leg 23 flattens out towards its end pole 23a to end in a wedge-like shape. This shape results in a smaller tendency for the body 21 to "overturn". Each leg 23 is provided with a cushion 25 constituting an integral part of the body 21. The cushion 25 is rounded in its shape and is arranged on the surface of the body 21 facing away from urethra. Providing the body 21 with such a bulge 25 results in higher compressive strength. Opposite to this bulge - on the outer side of the body 21 - there is possibly and primarily towards the front a recess 26 in each leg 3. The recess 26 causes the body 21 to cradle the urethra and imparts greater stability.

Additionally, on the side intended to face away from the urethra, the body 21 may be provided with ribs 27 at the periphery of the flexible base 22 and possibly extending fully or partially along the legs 23. This achieves a greater effect of restitution.

At the inner side of the flexible base 22, i.e., at the surface facing the opening of the vagina, a bevel, recess or shelf 24 serving as an abutment surface for an applicator 33 as shown in Figs. 14-18 may possibly be provided. The distal insertion end of the applicator is then positioned on the abutment surface 24. A string 28 fastened to each leg 3 is pulled back, whereby the body 21 folds about the applicator.

The body 21 is then inserted into the vagina by means of the applicator simultaneously with maintaining the pull in the string 28, and after positioning, the applicator is removed simultaneously with a cessation in the pull of the string 28. Then the body 21 will attempt to unfold in the same manner as described above. All other things being equal, the cushions 25 will impart greater compressive strength to the body 21.

The thickness of the legs 23 of the body and the flexible base 22 is in the interval of 20-50 mm, preferably 25-35 mm, while the length of the legs 23 these being measured as the distance between the end point (a) of a leg and the point (b) determined as the point at which the axes of symmetry of the legs intersect each other, is in the interval of 30-70 mm, preferably 40-50 mm, and where these dimensions are measured with the device 21 in a humidified state.

The width of the device is in the interval of 10-40 mm, preferably 15-25 mm (also measured in a humidified state).

Fig. 13 shows the device of Figs. 7-12 in its position of use.

When the body 21 is positioned in the vagina 29, one leg with its full surface bears against the vaginal anterior wall 30 and supports the neck 31 of the bladder, whereby continence is achieved. The other leg bears against the posterior wall 32 of the vagina. Thus, the device does not completely fill the vagina.

The compressive strength of the body is in the interval of 5-40 N - preferably 10-20 N - at a compression of

the body to 50 per cent of its thickness measured before compression. The force of restitution of the body is in the interval of 1-10 N - preferably 1-5 N (said values for the device in a humidified state).

The density of the material is in the interval of 0.15-0.30 g/cm³, preferably about 0.2 g/cm³.

Suitable materials for forming the above embodiments of the device are preferably formalized polyvinyl alcohol and polyurethane, but other materials may also be applied.

A suitable polyurethane material is prepared by mixing a prepolymerized polyurethane with water. 0.5-3 per cent, preferably 1-2 per cent, of a surface active additive has been added to the aqueous phase. A suitable surface-active additive is, for example, Emulgade 1000 Ni from Henkel. The polyurethane may be Hypol 2002 from Hampshire Chemical Corporation. The mixing ratio between the polyurethane component and the aqueous phase is selected so that there is an excess of polyurethane of 0-20 per cent - preferably 8-12 per cent. The material has the property that it expands by about 30 per cent when it is humidified, and it is a compressible, elastic material.

By manufacturing the body from this material, it is possible to obtain a saving on packaging, as the body takes up less space in a dry state than in the humidified state of use, and the body possesses good material properties rendering it pleasant for the user to utilize the body.

Figs. 14-18 show two embodiments of an applicator for use in the insertion of the above-described embodiments of the incontinence device into the vagina. In Figs. 14-17, the applicator comprises an elongated member 33 having a proximal end forming a finger grip 34 and a substantially distal end portion 35 being formed for abutment with the recess 24 at the rearwards facing side of the base 22 between the legs 23.

In the embodiment of Figs. 14-17, the member 33 has a substantially double concave, relatively flat cross-sectional profile along substantially most of its length. At the proximal end, the finger grip 34 is formed by means of a rib shape. To reduce friction and facilitate removal of the applicator after arrangement of the device in the vagina, the distal end portion 35 is formed with smooth, plane or possibly slightly convex sides of the cross-sectional profile, as shown in Fig. 17.

In the embodiment of Fig. 18, the applicator comprises a cylindrical body 36 which is open at both ends and formed for receiving an incontinence device as shown in Figs. 7-12 in its elastically compressed insertion state with the flexible base 22 facing towards one open end of the member 36, which end is positioned in the opening of the vagina when the applicator is used. An elongated member 37 comprises at its proximal end a piston-like element 38, which fits the internal diameter of the cylindrical body 36 and is intended for insertion at the opposite end of the body 36, and a substantially rod-shaped distal end portion 39 which may be formed in

the same manner as in the embodiment of Figs. 14-17. The piston-like element comprises a handle part projecting outside the applicator. In both embodiments, the distal insertion end 35, 39, respectively, may be designed for abutment also with the recesses 4 or 14 in the embodiments shown in Figs. 1-5. At a pull in the string 5, 15 or 28, the body will fold and be squeezed around the applicator, whereby the insertion is facilitated. In the embodiment of Fig. 18, the cylindrical body 36 may have an internal rib-shaped wall 40 to facilitate insertion, whereby the contact surface against the elastically deformed incontinence device is reduced and friction is lowered. The same effect may be obtained by means of a PTFE coating on the internal wall of the body.

Claims

1. A device for prevention of involuntary urination in a female, comprising an elastic body (1, 11, 21) made of a compressible material designed for arrangement in the vagina for compressive action on and support of the neck of the bladder, said body including at least two projecting legs (3, 13, 23) joined in a flexible base (2, 12, 22) and is dimensioned in such a way that in the non-deformed state of the body, the longest distance between the free ends of at least two legs exceeds the distance between the anterior wall and the posterior wall of the vagina, so that after insertion of the body into the vagina in an elastically deformed state with the legs bent in a direction towards each other, an active pressure is exerted on the neck of the bladder, characterized in that the body (1, 11, 21) is made of a porous material having such a compressibility that, at a compression of each leg to 50 per cent of its total thickness measured before compression, the compressive strength of the body is in the interval of 5-40 N, preferably 10-20 N, so that, by deformation of the legs in said elastically deformed insertion state to come into contact with each other on the mutually facing sides, the compressible material is compressed to provide an increased elastic force of restitution in the interval of 1-10 N - preferably 1-5 N.
2. A device according to claim 1, characterized in that the legs (3, 13, 23) diverge at an angle between the axes of symmetry of the legs of more than about 30 degrees.
3. A device according to claim 1 or 2, characterized in that the angle (A) between the legs (3, 13, 23) is smaller than 180° and is preferably 90-150°.
4. A device according to claims 1, 2 or 3, characterized in that the body comprises three legs (13).

5. A device according to any one of the preceding claims, **characterized** in that the legs (3, 13) and the base (2, 12) have a substantially circular cross-section.
6. A device according to any one of claims 1-4, **characterized** in that the legs (23) are wedge-shaped.
7. A device according to any one of claims 1-4 or 6, **characterized** in that on the side which is intended to face the urethra when the body is inserted in the vagina, each leg (23) is provided with a recess (26) and on the opposite side with a cushion (25) constituting an integral part of the leg.
8. A device according to claim 7, **characterized** in that on the side intended to face away from the urethra, the body (21) is provided with ribs (27) in the periphery of the part comprising the flexible base (22) and fully or partially on the periphery of the legs (23), which ribs constitute an integral part of the device.
9. A device according to any one of the preceding claims, **characterized** in that the body is hollow.
10. A device according to any one of the preceding claims, **characterized** in that the body (1, 11, 21) is fully or partially coated with an elastic polymer film, such as polyethylene, polypropylene or polyvinyl chloride.
11. A device according to any one of the preceding claims, **characterized** in that the body (1, 11, 21) is formed in polyurethane or polyvinyl alcohol.
12. A device according to any one of the preceding claims, **characterized** in that the device is manufactured from a material the density of which is in the interval of 0.15-0.30 g/cm³ - preferably about 0.20 g/cm³.
13. The combination of a device according to any of the preceding claims and an applicator for use in the insertion thereof into the vagina, **characterized** in that the device comprises a bevel or a recess (4, 14, 24) in the angle between the projecting legs (3, 13, 23), and that the applicator comprises an elongated member with a proximal end and with a substantially rod-shaped distal end portion (35) for abutment with said bevel or recess (24) for arrangement of the device in the vagina.
14. The combination according to claim 13, **characterized** in that the proximal end of the applicator is provided with a finger grip.
15. The combination according to claim 13, **character-**

ized in that the proximal end of the applicator forms a piston-like element, which fits into one end of a substantially cylindrical body (36) which is open at both ends and is formed for receiving said device in its elastically deformed insertion state with the flexible base (22) facing towards the other open end of the body, whereby the piston-like element comprises a handle part (38) projecting outside the cylindrical body (36).

16. The combination according to claim 15, **characterized** in that at the internal wall (40) of the cylindrical body (36) means are provided for reducing friction against the device.
17. The combination according to any one of claims 13-16, **characterized** in that the distal end portion (35) of the applicator is formed with smooth sides for reducing friction against the mutually facing sides of the legs (3, 13, 23) of the device.

Patentansprüche

1. Vorrichtung zur Vermeidung des unbeabsichtigten Harnlassens bei Frauen, umfassend einen aus zusammendrückbarem Material hergestellten elastischen Körper (1, 11, 21), der zwecks Zusammendrücken in Richtung zum Blasen Hals und Auflage des Blasen Halses zum Anbringen in der Vagina vorgesehen ist, wobei dieser Körper zumindest zwei in einer elastischen Unterlage (2, 12, 22) verbundene, vorstehende Schenkel (3, 13, 23) umfasst und derart ausgestaltet ist, dass im nicht deformierten Zustand des Körpers der längste Abstand zwischen den freien Enden von mindestens zwei Schenkeln grösser ist als der Abstand zwischen der vorderen und hinteren Vaginalwand, so dass nach Einsetzen des Körpers in der Vagina in einem elastisch deformierten Stand, in dem die Schenkel in Richtung zueinander gebogen sind, auf den Blasen Hals ein aktiver Druck ausgeübt wird, dadurch **gekennzeichnet**, dass der Körper (1, 11, 21) aus porösem Material einer solchen Kompressibilität hergestellt ist, dass bei Kompression eines jeden Schenkels auf 50% dessen gesamter Dicke vor der Kompression die Druckfestigkeit des Körpers im Bereich 5-40 N, vorzugsweise 10-20 N, liegt, so dass durch Deformation der Schenkel auf erwähnten elastisch deformierten Zustand des Einsetzens, wo die gegenseitig zuwendenden Seiten miteinander in Berührung kommen, das zusammendrückbare Material zusammengepresst ist, um eine erhöhte elastische Rückbildungskraft im Bereich 1-10 N, vorzugsweise 1-5 N, zu verleihen.
2. Vorrichtung nach Anspruch 1, dadurch **gekennzeichnet**, dass die Schenkel (3, 13, 23) zwischen

den Symmetrieachsen der Schenkel bei einem Winkel von mehr als etwa. 30° divergieren.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch **gekennzeichnet**, dass der Winkel (A) zwischen den Schenkeln (3, 13, 23) kleiner als 180° und vorzugsweise 90-150° ist. 5
4. Vorrichtung nach Anspruch 1, 2 oder 3, dadurch **gekennzeichnet**, dass der Körper drei Schenkel (13) umfasst. 10
5. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch **gekennzeichnet**, dass die Schenkel (3, 13) und die Unterlage (2, 12) einen im wesentlichen kreisförmigen Querschnitt aufweisen. 15
6. Vorrichtung nach einem der Ansprüche 1-4, dadurch **gekennzeichnet**, dass die Schenkel (23) keilförmig sind. 20
7. Vorrichtung nach einem der Ansprüche 1-4 oder 6, dadurch **gekennzeichnet**, dass nach Einsetzen des Körpers in die Vagina jeder Schenkel (23) auf der der Urethra zuwendenden Seite des Körpers mit einer Vertiefung (26) und auf der gegenüberliegenden Seite mit einem Kissen (25) ausgebildet ist, die einen integralen Teil des Schenkels darstellen. 25
8. Vorrichtung nach Anspruch 7, dadurch **gekennzeichnet**, dass der Körper auf der von der Urethra abgekehrten Seite (21) in der Peripherie des Teils der elastischen Unterlage (22) und ganz oder teilweise am Rande der Schenkel (23) mit Rippen ausgestattet ist, die einen integralen Teil der Vorrichtung darstellen. 30
9. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch **gekennzeichnet**, dass der Körper hohl ist. 35
10. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch **gekennzeichnet**, dass der Körper (1, 11, 21) ganz oder teilweise mit einem elastischen Polymerfilm, wie etwa Polyäthylen, Polypropylen oder Polyvinylchlorid beschichtet ist. 40
11. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch **gekennzeichnet**, dass der Körper (1, 11, 21) aus Polyurethan oder Polyvinylalkohol ausgebildet ist. 45
12. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch **gekennzeichnet**, dass die Vorrichtung aus einem Material hergestellt ist, dessen Dichte im Bereich 0,15-0,30 g/cm³, vorzugsweise etwa 0,20 g/cm³ ist. 50

13. Kombination einer Vorrichtung nach einem der vorhergehenden Ansprüche und eines Applikators zum Gebrauch beim Einsetzen der Vorrichtung in die Vagina, dadurch **gekennzeichnet**, dass die Vorrichtung im Winkel zwischen den vorstehenden Schenkeln (3, 13, 23) eine Schale oder eine Vertiefung (4, 14, 24) aufweist, und dass der Applikator ein längliches Glied mit einem proximalen Ende und einem im wesentlichen stabförmigen distalen Endteil (35) zum Anlegen an die Schale oder Vertiefung (24) und Anbringen der Vorrichtung in der Vagina umfasst.

14. Kombination nach Anspruch 13, dadurch **gekennzeichnet**, dass das proximale Ende des Applikators mit einem Fingergriff versehen ist.

15. Kombination nach Anspruch 13, dadurch **gekennzeichnet**, dass das proximale Ende des Applikators ein kolbenähnliches Element bildet, das in das eine Ende eines im wesentlichen zylinderförmigen Körpers (36) hineinpasst, welcher Körper an beiden Enden offen ist zur Aufnahme der Vorrichtung in deren elastisch deformierten Zustand, in der die elastische Unterlage (22) dem anderen offenen Ende des Körpers zuwendet, wobei das kolbenähnliche Element einen ausserhalb des zylinderförmigen Körpers (36) angeordneten Griff (38) umfasst.

16. Kombination nach Anspruch 15, dadurch **gekennzeichnet**, dass auf der Innenwand (40) des zylinderförmigen Körpers friktionsreduzierende Mittel vorgesehen sind.

17. Kombination nach einem der Ansprüche 13-16, dadurch **gekennzeichnet**, dass der distale Endteil (35) des Applikators mit glatten Seiten zur Reduzierung der Friktion der untereinander anliegenden Seiten der Schenkel (3, 13, 23) der Vorrichtung versehen ist.

Revendications

1. Dispositif pour empêcher les mictions involontaires chez la femme, comportant un corps élastique (1, 11, 21) constitué d'un matériau compressible et conçu pour mise en place dans le vagin pour exercer une action de compression sur le col de la vessie et pour supporter celui-ci, ledit corps comportant au moins deux branches saillantes (3, 13, 23) se rejoignant par une base flexible (2, 12, 22), et étant dimensionné de telle manière qu'à l'état non déformé du corps, la distance la plus grande entre les extrémités libres d'au moins deux branches est supérieure à la distance entre la paroi antérieure et la paroi postérieure du vagin, si bien qu'après insertion, dans le vagin, du corps à l'état élastiquement déformé avec les branches inflé-

- chies en direction l'une de l'autre, une pression active est exercée sur le col de la vessie, **caractérisé** en ce que le corps (1, 11, 21) est constitué d'un matériau poreux présentant une compressibilité telle que pour une compression de chaque branche allant jusqu'à 50 pour-cent de son épaisseur totale mesurée avant compression, la force compressive du corps se situe dans l'intervalle de 5 à 40 N, de préférence 10 à 20 N, si bien que par déformation des branches vers ledit état élastiquement déformé d'insertion pour les amener en contact l'une avec l'autre sur leurs faces mutuellement opposées, le matériau compressible se trouve comprimé pour fournir une force accrue de restitution élastique se situant dans l'intervalle de 1 à 10 N, de préférence 1 à 5 N.
2. Dispositif selon la revendication 1, **caractérisé** en ce que les branches (3, 13, 23) divergent d'un angle entre les axes de symétrie des branches supérieur à environ 30 degrés.
 3. Dispositif selon les revendications 1 ou 2, **caractérisé** en ce que l'angle (A) entre les branches (3, 13, 23) est inférieur à 180° et se situe, de préférence, entre 90 et 150°.
 4. Dispositif selon les revendications 1, 2 ou 3, **caractérisé** en ce que le corps comporte trois branches (13).
 5. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé** en ce que les branches (3, 13) et la base (2, 12) présentent une section transversale essentiellement circulaire.
 6. Dispositif selon l'une quelconque des revendications 1 à 4, **caractérisé** en ce que les branches (23) ont la forme d'un coin.
 7. Dispositif selon l'une quelconque des revendications 1 à 4 ou 6, **caractérisé** en ce que sur le côté prévu pour faire face à l'urètre, quand le corps est introduit dans le vagin, chaque branche (23) présente un renforcement (26) et, sur la face opposée, un coussin (25) formant partie intégrante de la branche.
 8. Dispositif selon la revendication 7, **caractérisé** en ce que sur le côté prévu pour faire face à l'urètre, le corps (21) est pourvu de nervures (27) dans la périphérie de la partie comprenant la base flexible (22) et totalement ou partiellement sur la périphérie des branches (23), lesdites nervures formant partie intégrante du dispositif.
 9. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé** en ce que le corps est creux.
 10. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé** en ce que le corps (1, 11, 21) est totalement ou partiellement recouvert d'un film de polymère élastique, comme par exemple polyéthylène, polypropylène ou chlorure de polyvinyle.
 11. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé** en ce que le corps est conformé dans du polyuréthane ou de l'alcool polyvinylique.
 12. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé** en ce que le dispositif est manufacturé à partir d'un matériau dont la densité se situe dans la gamme de 0,15 à 0,30 g/cm³ - de préférence environ 0,20 g/cm³.
 13. Combinaison d'un dispositif selon l'une quelconque des revendications précédentes et d'un applicateur permettant son introduction dans le vagin, **caractérisé** en ce que le dispositif comporte un biseau ou renforcement (4, 14, 24) dans l'angle entre les branches saillantes (3, 13, 23) et en ce que l'applicateur comporte une pièce allongée avec une extrémité proximale et une partie d'extrémité distale (35) essentiellement en forme de tige pour appui contre ledit biseau ou renforcement (24) pour mise en place du dispositif dans le vagin.
 14. Combinaison selon la revendication 13, **caractérisé** en ce que l'extrémité proximale de l'applicateur comprend une partie de préhension par les doigts.
 15. Combinaison selon la revendication 13, **caractérisé** en ce que l'extrémité proximale de l'applicateur forme un élément du type piston situé dans une extrémité d'un corps (36) essentiellement cylindrique, ouvert à ses deux extrémités, et conçu pour loger ledit dispositif dans son état élastiquement déformé d'insertion, la base élastique (22) étant orientée vers l'autre extrémité ouverte du corps, l'élément du type piston comportant une poignée (38) faisant saillie hors du corps cylindrique (36).
 16. Combinaison selon la revendication 15, **caractérisé** en ce que sur la face interne (40) du corps cylindrique (36) sont prévus des moyens réducteurs de friction contre le dispositif.
 17. Combinaison selon l'une quelconque des revendications 13 à 16, **caractérisé** en ce que la partie d'extrémité distale (35) de l'applicateur comporte des faces lisses pour réduire la friction entre les cotés des branches (3, 13, 23) du dispositif se faisant mutuellement face.

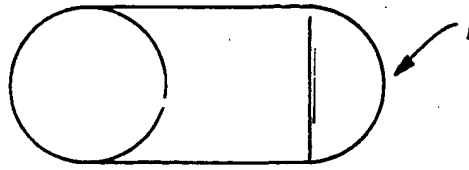


FIG. 1

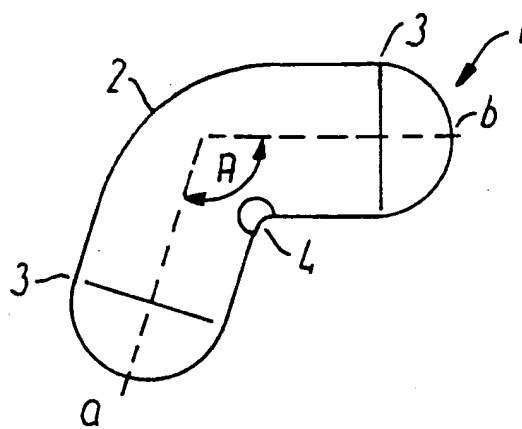


FIG. 2

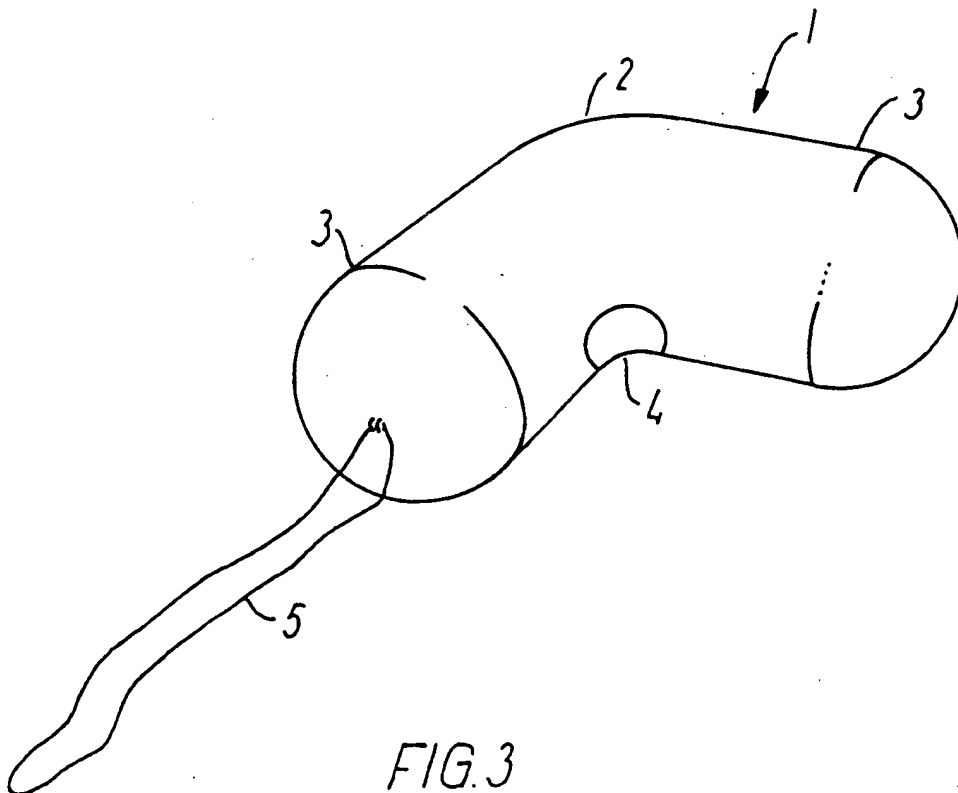


FIG. 3

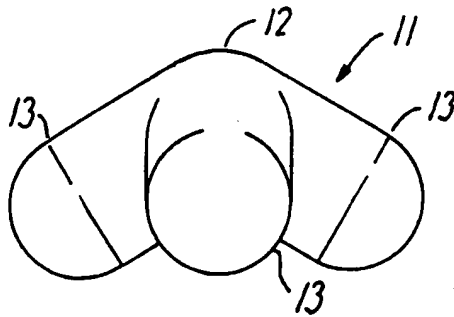


FIG. 4

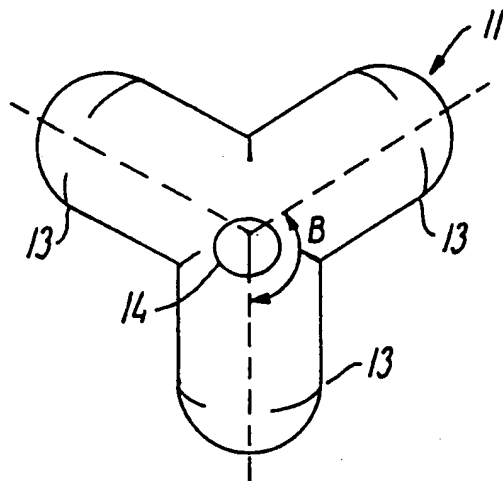


FIG. 5

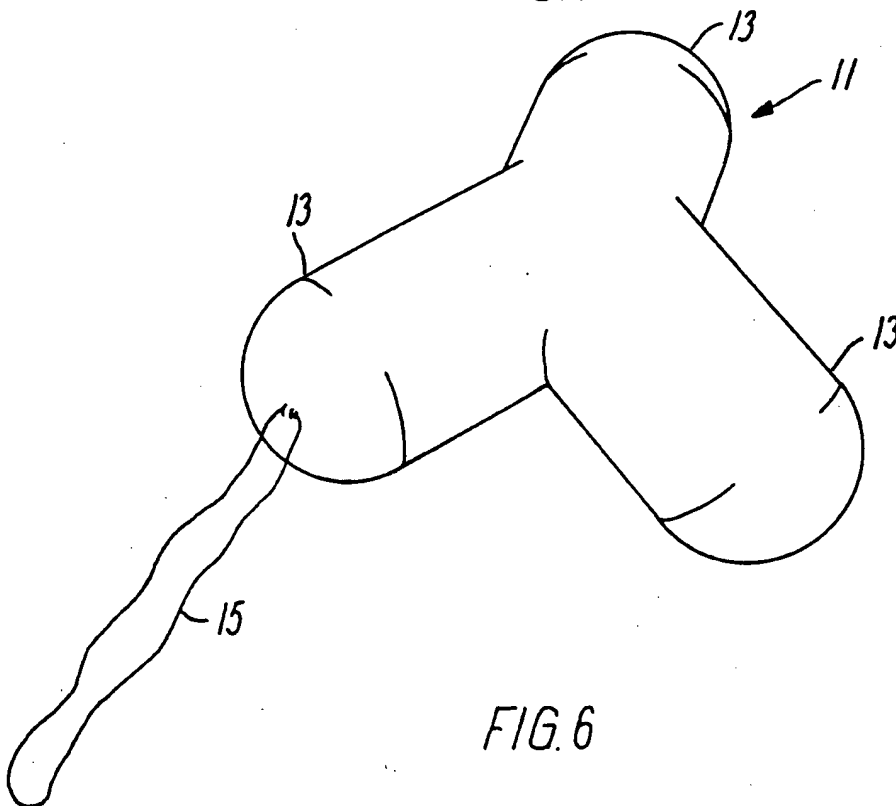


FIG. 6

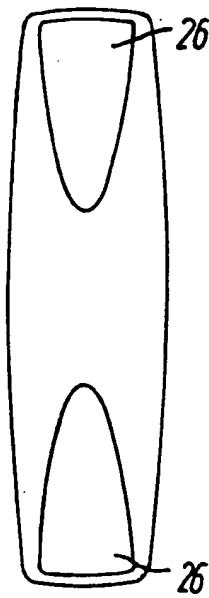


FIG. 7

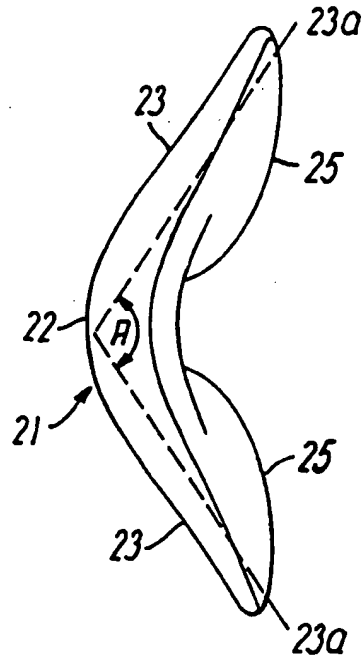


FIG. 8

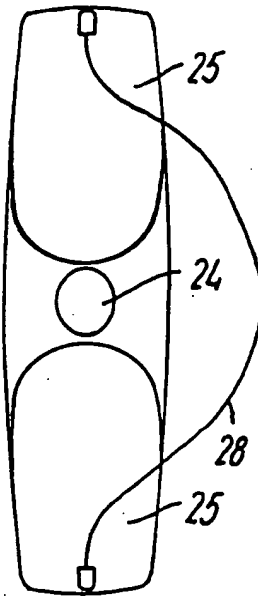


FIG. 9

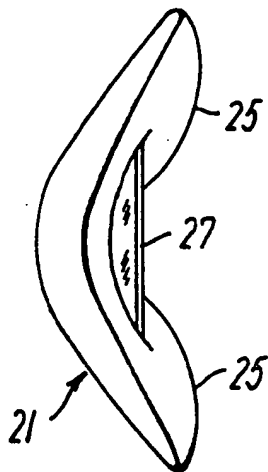


FIG. 10

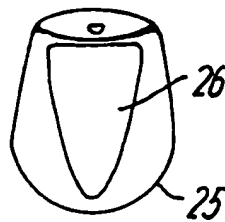


FIG. 11

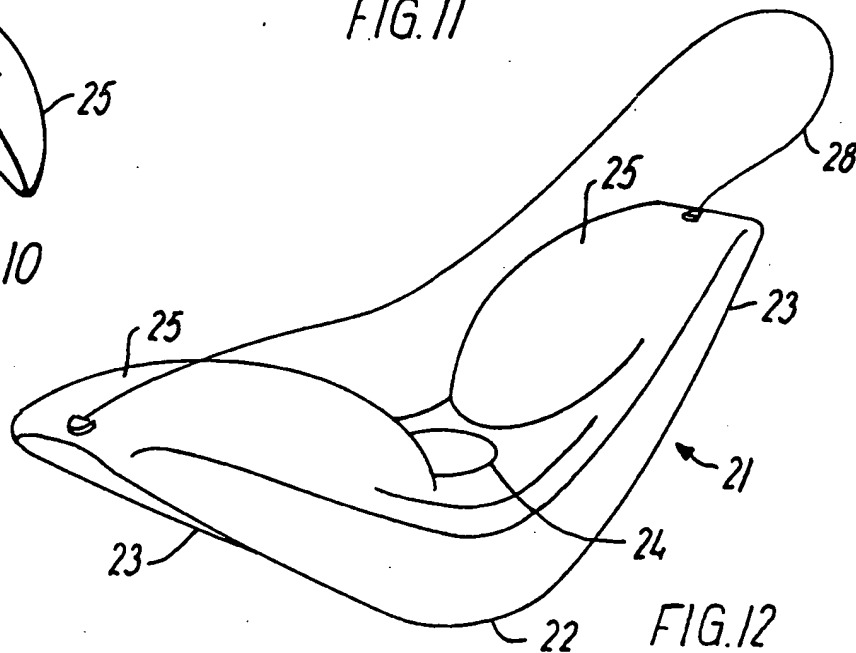


FIG. 12

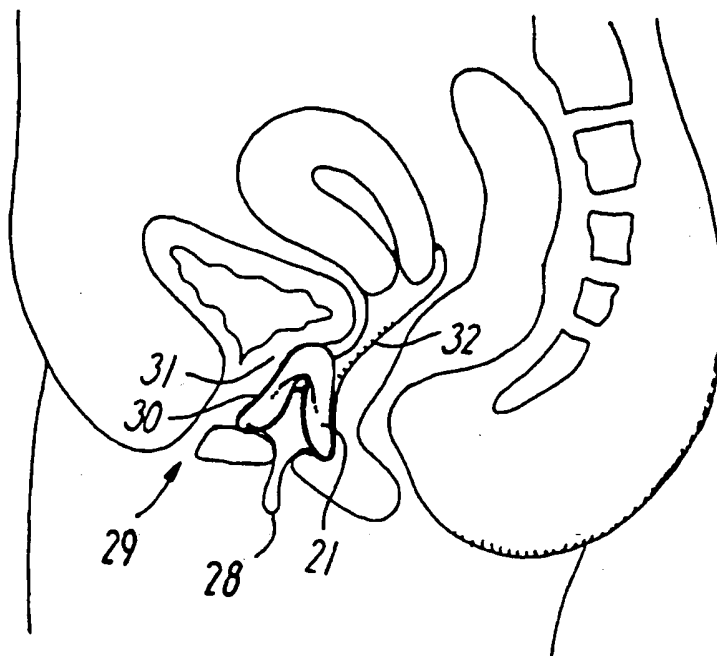


FIG. 13

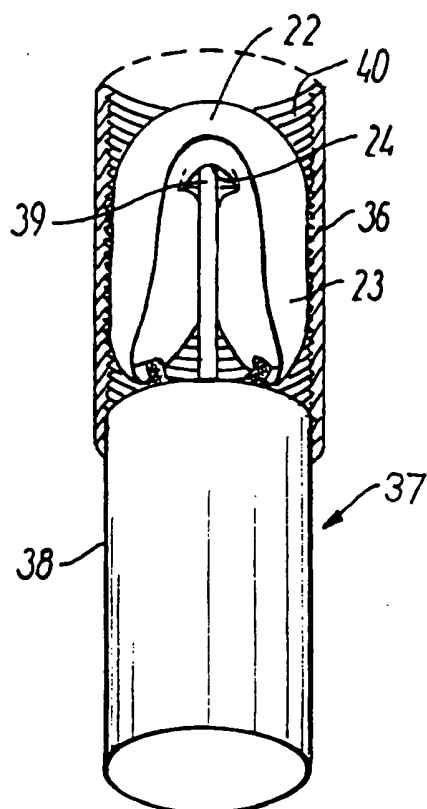


FIG. 18

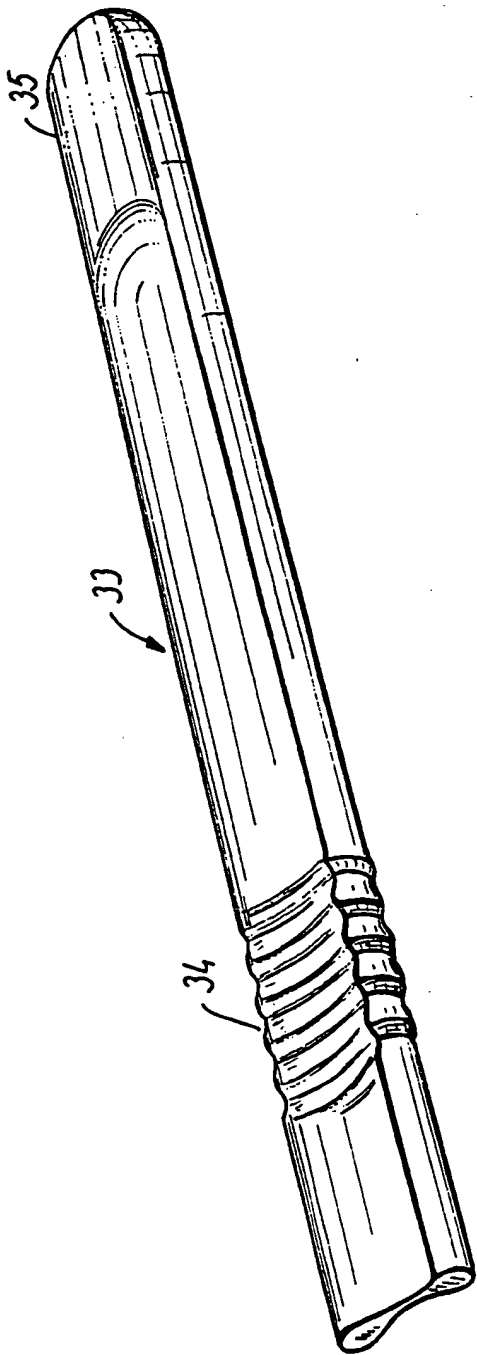


FIG. 14

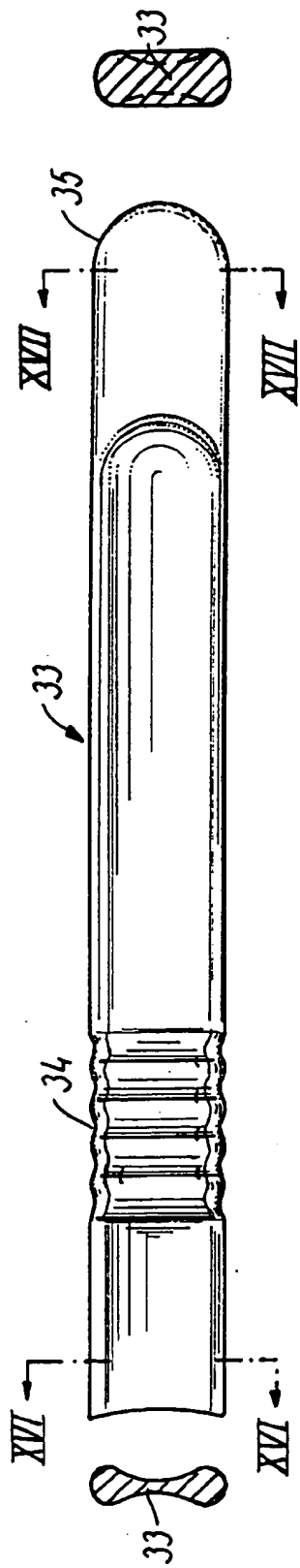


FIG. 15

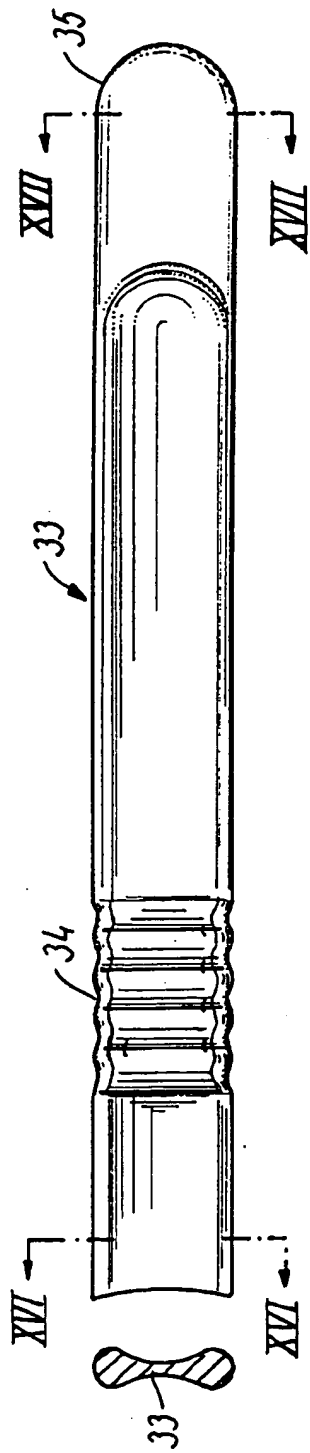


FIG. 16

FIG. 17

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